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510(k) Summary of Safety and Effectiveness

1. **Sponsor Name:** ConMed Endoscopic Technologies, Inc.
One Executive Drive, Suite 101
Chelmsford, MA 01824
Telephone: 978-934-7832
Fax: 978-934-7854
Contact Individual: Karen Provencher
Sr. Regulatory Affairs Specialist

2. **Device Name:** ConMed Deuce Polypectomy Snare

3. **Identification of Predicate or Legally Marketed Device:**
ConMed Beamer™ Snare Probe cleared under K081580 on June 20, 2008
Cook Sonnet™ Polypectomy Snare cleared under K050294 on March 31, 2005
Medi-Globe Polypectomy Snare cleared under K943935 on May 26, 1995
Polypectomy Snares cleared under K820430 on April 8, 1982

4. **Device Description:**
The ConMed Deuce Polypectomy Snare is a sterile, single patient use, disposable device used in conjunction with an electrosurgical generator for the delivery of electrosurgical current through a flexible endoscope to a stainless steel wire snare at the operative site for endoscopic resection of a polypoid lesion.

The snare consists of a non-detachable handle with a sliding finger ring mechanism for retracting/extending the distal snare loop. An external sheath covers the snare loop cable and is attached to the distal portion of the snare handle. Within the handle, an electrode completes the circuit between the electrosurgical unit and the snare loop.

The polypectomy snares are manufactured in 230cm sheath lengths with a 2.3mm outer diameter in a variety of different loop configurations.

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5. **Intended Use:**
The ConMed Polypectomy Snares may be used in conjunction with an electrosurgical generator for endoscopic resection of a polypoid lesion.

6. **Comparison of Technological Characteristics:**
The ConMed Polypectomy Snares are substantially equivalent to the predicate devices both in intended use, technological characteristics and materials.

7. **Performance Testing:**
Bench testing has been performed to demonstrate equivalence of the ConMed Polypectomy Snares to their predicate devices. All testing passed the predetermined performance specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 22 2009

Ms. Karen Provencher
Senior Regulatory Affairs Specialist
ConMed Endoscopic Technologies
One Executive Drive, Suite 101
CHELMSFORD MA 01824

Re: K091355
Trade/Device Name: ConMed Deuce Polypectomy Snares
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Regulatory Class: II
Product Code: FDI
Dated: May 7, 2009
Received: May 8, 2009

Dear Ms. Provencher:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

C. INDICATION FOR USE

510(k) Number (if known) K091355

Device Name: ConMed Deuce Polypectomy Snare

Indication for Use:

May be used in conjunction with an electrosurgical generator for endoscopic resection of a polypoid lesion.

Prescription Use X AND/OR Over the Counter Use _____
(Per 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K091355